IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

INGENUS PHARMACEUTICALS, LLC, and LEIUTIS PHARMACEUTICALS LLP, Plaintiffs, v. NEXUS PHARMACEUTICALS, INC., Defendant.	Case No. 22–cv–02868 Judge Mary M. Rowland

MEMORANDUM OPINION AND ORDER

Plaintiff Ingenus Pharmaceuticals, LLC ("Ingenus") sued Defendant Nexus Pharmaceuticals, Inc. ("Nexus"), alleging that Nexus infringed U.S. Patent No. 10,993,952 (the "952 Patent").[1] Before the Court now is Ingenus's motion for summary judgment on their infringement claim and Nexus's motion for summary judgment on on the basis that the '952 Patent is invalid. For the reasons stated below, Ingenus's motion for summary judgment [130] is denied and Nexus's motion for summary judgment for invalidity is granted [132].

SUMMARY JUDGMENT STANDARD

Summary judgment is proper where "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). A genuine dispute as to any material fact exists if "the evidence is such that a

[1] Plaintiff Leuitis was dismissed from the action for lack of standing. [206].

reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The substantive law controls which facts are material. *Id*. After a "properly supported motion for summary judgment is made, the adverse party 'must set forth specific facts showing that there is a genuine issue for trial.'" *Id*. at 250 (quoting Fed. R. Civ. P. 56(e)).

The Court "consider[s] all of the evidence in the record in the light most favorable to the non-moving party, and [ ] draw[s] all reasonable inferences from that evidence in favor of the party opposing summary judgment." *Logan v. City of Chicago*, 4 F.4th 529, 536 (7th Cir. 2021) (quotation omitted). The Court "must refrain from making credibility determinations or weighing evidence." *Viamedia, Inc. v. Comcast Corp*., 951 F.3d 429, 467 (7th Cir. 2020) (citing *Anderson*, 477 U.S. at 255). In ruling on summary judgment, the Court gives the non-moving party "the benefit of reasonable inferences from the evidence, but not speculative inferences in [its] favor." *White v. City of Chicago*, 829 F.3d 837, 841 (7th Cir. 2016) (internal citations omitted). "The controlling question is whether a reasonable trier of fact could find in favor of the non-moving party on the evidence submitted in support of and opposition to the motion for summary judgment." *Id.*

BACKGROUND

I. The '952 Patent

On July 30, 2020, the United States Food and Drug Administration ("FDA") approved Plaintiffs' New Drug Application ("NDA") No. 212501, which was for the sale and manufacture of a cyclophosphamide solution for intravenous use. [164] ¶ 5. Cyclophosphamide is used for the treatment of malignant diseases such as

lymphomas, myeloma, leukemia, breast carcinoma, and more. [164] ¶ 8. Plaintiffs were not required to conduct clinical trials when they filed their NDA because they relied on established safety and efficacy data for an injectable cyclophosphamide formulate first made available in 1959. [164] ¶ 9.

The '952 Patent, titled "Stable ready to Use Cyclophosphamide Liquid Formulations," was issued by the U.S. Patent and Trademark Office on May 4, 2021. [164] ¶ 11. The '952 Patent states that its formulations were "tested for stability under accelerated condition for a period of 1 week at 40° C/75% RH." [1-1] at 3. The patent further summarizes the "stability data" of that test as measured by the formulations of various impurities. [1-1] at 3. The '952 Patent separately states in its specification that its "compositions of Cyclophosphamide were found to be stable when stored at 2° C. to 8° C. temperature." [159] ¶¶ 4-5. The prosecution history of the '952 Patent discusses stability in terms of degradation, impurity formation, decomposition, solution stability, and storage stability. [159] ¶ 7. The patent contains four claims directed to formulations of cyclophosphamide which all require a stable liquid parenteral formulation. [159] ¶¶ 11-12.

The prosecution history of the '952 Patent demonstrates that it was rejected numerous times by the patent examiner for obviousness over the prior art. *See* [69-1] at 377-84, 385-92, 451-66, 456-60; 409 (explaining that claims were rejected "as being anticipated/obvious over" prior art formulations); 437 (explaining rejection because prior art "teaches stable liquid parenteral formulations of the very same drug, cyclophosphamide, in the very same solvents . . . as instantly claimed.").

Ultimately, the patent was approved after the examiner determined that the prior art did not anticipate or render obvious the claimed compositions of cyclophosphamide because of its "better stability (less impurities formed and smaller % assay drop after 1 week at 40° C.)". [69-1] at 561.

II. Nexus's Accused Cyclophosphamide Products

On December 28, 2021, Nexus submitted its Abbreviated New Drug Application No. 216783 ("ANDA"), which sought FDA approval for cyclophosphamide solution for intravenous injection. [159] ¶¶ 28. Nexus's proposed drug product contains as formulation ingredients cyclophosphamide, ethanol, propylene glycol, polyethylene glycol, and monothioglycerol, as does Ingenus's product. [159] ¶ 28. The FDA approved Nexus's ANDA on October 29, 2024. [154] ¶ 4.

III. Claim Construction

The parties engaged in claim construction before the Court on August 25, 2023. [154] ¶ 5. There, Nexus argued that the term "stable" as used in all claims of the '952 Patent is indefinite for failing to provide a reasonable scope of the patent's claims. [154] ¶ 5. Plaintiffs argued that because the term appeared in the preamble of the claims, it did not require construction. [154] ¶ 6. The Court disagreed with Plaintiffs, noting that because the prosecution history made clear the patent was only awarded because of its improved stability, the term was limiting. The Court deferred construction of the term and resolution of Nexus's argument that the term was indefinite until the parties could present a more developed factual record.

ANALYSIS

I. Invalidity

Nexus argues that the '952 Patent is invalid because the term "stable" is indefinite. "A patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). To determine indefiniteness, courts examine "the patent record—the claims, specification, and prosecution history—to ascertain if they convey to one of skill in the art with reasonable certainty the scope of the invention claimed." *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015). Definiteness is a question of law. *Sonix Tech. Co. v. Publications Int'l, Ltd.*, 844 F.3d 1370, 1376 (Fed. Cir. 2017). "Any fact critical to a holding on indefiniteness . . . must be proven by the challenger by clear and convincing evidence." *Intel Corp. v. VIA Techs., Inc.*, 319 F.3d 1357, 1366 (Fed. Cir. 2003).

Claim terms are generally given their ordinary and customary meaning, which is the meaning it would have to a person of ordinary skill in the art ("POSA") at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005). A POSA "is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id.* at 1313. "Because claim terms are normally used

consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims." *Id*. at 1314.

As noted above, the '952 Patent uses the word "stable" in several different ways. In the specification, the patent states, without further explanation, that the "inventive compositions of Cyclophosphamide were found to be stable when stored at 2 C°. to 8 C°. temperature." [1-1] col. 3. The parties and their experts refer to this as "Refrigerated Conditions." Separately, the patent explains that its formulations were "tested for stability under accelerated condition for a period of 1 week at 40 C°. and 75% RH," referring to room humidity. [1-1] col. 4. The patent then summarizes the "stability data" of the invention when tested under these conditions in Table 1, which is reproduced below:

TABLE 1

Stability data of the invention formulation

		Stability Data at 40° C./75% RH				
		Example 2		Example 4		Example 5
S. No.	Impurities	Initial	1 Week	Initial	1 Week	1 Week
		Impurities (% w/w)				
1	Impurity-A	ND	ND	0.01	0.05	ND
2	Impurity-B	0.06	0.18	0.05	0.19	0.21
3	Impurity-D	ND	ND	ND	ND	ND
4	Impurity-E	ND	ND	ND	0.45	0.65
5	Impurity-G	ND	ND	ND	1.24	1.22
6	Total	0.07	1.87	0.06	2.01	2.33
7	Assay (%)	101.6	101.9	102.1	98.9	99.7

ND: Not detectable

All four claims in the patent require a stable liquid parenteral formulation of cyclophosphamide. [159] ¶¶ 11-12. Claim 1 describes a stable formulation wherein after storage for 1 week at 40° C/75% RH, decomposition to form any of impurities A, B, and D as less than 0.5%. [1-1] at 5. The parties and their experts generally refer

to this as an "Accelerated Conditions Test." [161-4] at 36:20 – 37:11. On its face, Claim 1 says nothing about refrigerated conditions. Claim 2 is a formulation of claim 1, further comprising an antioxidant, and Claim 3 is a formulation of Claim 2 comprising a specific range of monothioglycerol. [1-1] at 5. Claim 4 claims a "stable liquid parenteral formulation" but does not specify whether it is stable under the Accelerated Conditions Test or in Refrigerated Conditions.

Nexus relies primarily on Ingenus's experts, Dr. Rabinow and Dr. Yaman, to argue the term stable is indefinite and thus does not provide a POSA with reasonable certainty of the scope of the invention claimed.[2] Both experts agree that there is no single definition of "stable" but generally claim that a POSA would understand the term in reference to cyclophosphamide in terms of the following "aspects": 1) degradation, 2) impurity formation, 3) decomposition, 4) solution stability, and 5) storage stability. *See* [135-1] ¶ 41, [135-3] ¶ 219. Both experts also describe as "aspects" of stability 1) "control impurities within acceptable limits,"[3] 2) "have less

[2] Ingenus argues that Nexus cannot rely on Ingenus's own expert reports because they were unsigned and thus lack foundation and are inadmissible hearsay. [153] at 2-3. As to foundation, counsel for Nexus signed an affidavit swearing that the expert reports are true and accurate copies or excerpts of the originals. [133]. This is sufficient in itself to establish foundation under Rule 901(b)(1). Ingenus's expert Dr. Rabinow also authenticated his reports in his deposition. [161-4] at 13:23 – 14:11 (authenticating opening report); 77:10-22 (authenticating reply report). As to hearsay, the statements are admissible as statements by a party opponent pursuant to Rule 801(d)(2). *Samaritan Health Ctr. v. Simplicity Health Care Plan*, 459 F. Supp. 2d 786, 799 (E.D. Wis. 2006) ("[B]ecause [defendant] proffers its opponent's expert report against that opponent, the report can be considered an admission by a party-opponent, which falls outside the hearsay definition."); *Rawers v. United States*, 488 F.Supp.3d 1059, 1084 n.29 (D.N.M. 2020) (collecting cases). Nexus may thus rely on Ingenus's expert reports to support its motion.

[3] For the purposes of this aspect, it is not clear to the Court whether only impurities A, B, and D must be within acceptable limits or whether all the impurities contemplated in the patent's Table 1 must be below acceptable limits. It is also not clear to the Court what those acceptable limits are, as Table 1 shows impurity G at over 1% after one week in two examples.

than 0.5% of impurities A, B, and D," 3) "are storage stable after testing at 40° C, 75% RH, 7 days," and 4) "are stable when stored at 2-8° C." Nexus's expert, Dr. Donovan, agrees that there "are different types of stability testing, including long-term stability testing, accelerated stability testing, and stress testing." [133-5] ¶ 249.

Nexus argues that because Ingenus's experts are unable to prove one definition of stable exists, the term is "conclusively" indefinite. *See* [134] at 11-12. Here, the Court disagrees. The definiteness requirement "mandates clarity" but it also recognizes that "absolute precision is unattainable." *Nautilus*, 572 U.S. at 910. Rather, a patent must only "be precise enough to afford clear notice of what is claimed, thereby appris[ing] the public of what is still open to them," such that there is not a "zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims." *Id*. at 909-10 (cleaned up).

The question, then, is not whether "stable" has a singular definition; the question is whether the patent provides a POSA notice of what is claimed by the word "stable" such that a POSA can know when they risk infringement. On this front, Nexus has established by clear and convincing evidence that an impermissible "zone of uncertainty" exists. A POSA could not be reasonably certain under which test or what conditions the claimed formulations are stable, and thus under which test or conditions a similar invention could be said to infringe on the patent's claims.

Plaintiff's expert Dr. Rabinow's own uncertainty is telling. In his opening report, Dr. Rabinow appeared to believe that, to infringe on the patent, an accused product must be stable under the Accelerated Conditions Test *and* under Refrigerated

Conditions. [135-1] ¶¶ 54 – 57. Dr. Donovan, Nexus's expert, opined that a POSA would be unsure of which test applied to each claim, and that this could "create[] a situation where a product would be 'stable' under one aspect of the invention, but not 'stable' under another . . . leav[ing] the public unsure as to whether the designed cyclophosphamide product is inside or outside the scope of the claims of the '952 patent." [145-2] ¶ 9. Dr. Rabinow responded to Dr. Donovan's conclusion by disavowing his earlier approach. He stated that a POSA *would* be sure whether their product is in or outside the scope of the patent's claims because stability under Refrigerated Conditions "is not claimed," and the product would only need to satisfy the definition of stability under the Accelerated Conditions Test to infringe. [161-2] ¶ 26. But during his deposition, Dr. Rabinow changed his opinion again, arguing that the patent *did* claim stability under Refrigerated Conditions. [161-4] at 131:13-8 ("Q: So it's now your opinion that stability upon 2 to 8 degrees Celsius is explicitly claimed in the '952 Patent, is that correct? A: Yes"). During his deposition, Dr. Rabinow also testified for the first time, and in contradiction with his earlier reports, that stability against loss of potency was claimed by the patent. [161-4] at 133:6-9 ("Q: That's another change in your opinion in Paragraph 26 of your reply report, correct? A: I guess so.") (objections omitted).

Ingenus argues that "stable" cannot be indefinite because "Nexus nowhere suggests that different results are obtained when a formulation is subjected to a specific test whose parameters are well defined, e.g., 40˚C., 75% RH for 7 days." [153] at 13. But that captures Ingenus's problem: Dr. Rabinow does not agree that the

Accelerated Conditions Test *is* the specific test the claimed formulations are subjected to. To the extent that Dr. Rabinow is wrong, and the claimed formulations do *not* need to be tested for stability under Refrigerated Conditions, then it cannot be said that a person of ordinary skill in the art can be reasonably sure of the patent's scope when that scope cannot be ascertained by Ingenus's own expert.

To the extent that Dr. Rabinow is correct that, contrary to the position of Ingenus's counsel, each claim must also be tested under Refrigerated Conditions, Ingenus has another problem. Other than the temperature, the patent provides no information about what parameters that test would involve — not the length of time the test should last, the acceptable impurities thresholds, or which impurities to test. Ingenus argues that a POSA could look to FDA standards to determine what those parameters would be and notes that FDA guidance "describes other kinds of stability testing, including photostability testing, stability testing on the container closure system, storage stability testing, etc." [153] at 8.[4] But the patent does not explain which of these kinds of tests were conducted in Refrigerated Conditions or what metrics were used to measure stability. Dr. Yaman, Ingenus's other expert, similarly stated that the word "stable" as used in the patent would cover liquid forms of cyclophosphamide "that are resistant to the loss of cyclophosphamide over time, whether through degradation, decomposition, hydrolysis, or some other means, as measured by *any* of

[4] Ingenus's reliance on FDA guidance is further complicated in that none of the FDA tests that Ingenus points to appear in the patent itself. Citing to FDA guidance, Ingenus says that the FDA uses "the same accelerated aging test temperature and relative humidity described in the '952 Patent." [153] at 8 (emphasis in original). But the document that Ingenus cites to describes an accelerated aging test that lasts for six months, not one week, as the test in the patent describes. [156-6] at 5.

the methods disclosed, referred to, or understood by a person of ordinary skill in the art." [155-11] ¶ 60 (emphasis added). But this could create exactly the kind of scenario where whether a product is within the scope of the patent depends on the definition of "stable" that is used, and it thus creates a "zone of uncertainty" as to what is patented. *Nautilus*, 572 U.S. 898 at 899; *see also Inguran, LLC v. ABS Glob., Inc.*, No. 17-CV-446-WMC, 2019 WL 943515, at *8 (W.D. Wis. Feb. 26, 2019) ("While a 'you'll know it when you see it approach' may work in other areas of law, this approach is incompatible with the requirement that a patent claim informs with reasonable certainty those skilled in the art about the scope of the invention.").

To put a finer point on it, if a formulation of cyclophosphamide results in decomposition to form any of impurities A, B, and D as less than 0.5% after one week in Accelerated Conditions, but does *not* retain the same degree of impurity formation under Refrigerated Conditions, Ingenus and one of its experts are at odds over whether that formulation would infringe on the patent. Further, neither the patent nor its prosecution history are clear whether the 0.5% impurity threshold is relevant to evaluating stability under Refrigerated Conditions.

A review of Federal Circuit caselaw confirms that "stable," as used in the '952 Patent, is indefinite. The word "stable" in the '952 Patent is like how patentees used the term "molecular weight" in *Teva*. There, the Federal Circuit reversed a district court and held that "molecular weight" was indefinite because it could correspond to multiple different measures. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1338 (Fed. Cir. 2015). The court explained that because (1) "molecular weight" could

be ascertained by any of three possible measures, (2) use of different measures could yield a different result, and (3) neither the claims nor specification indicate which measure to use, there "was not reasonable certainty that molecular weight should be measured using" the measure put forth by the plaintiffs. *Id* at 1344-45.

Similarly, in *HZNP Medicines*, the Federal Circuit considered whether the term "better drying time," as used in a patent for topical ointments meant to treat osteoarthritis, was indefinite. *HZNP Medicines LLC v. Actavis Lab'ys UT, Inc.*, 940 F.3d 680, 696 (Fed. Cir. 2019). The patent there provided two tests to measure drying time. *Id*. The specification provided that, under one test, the patented product would be drier 30 minutes after application than the previous art. *Id*. Relevant to the other test, the patent provided quantitative comparisons that measured the residual weight of formulations in comparisons between prior art formulations and the patented formulation. *Id*. at 696-97. The district court determined, and the Federal Circuit affirmed, that the two tests did "not provide consistent results at times" because a given formulation might satisfy the results of one test but not the other, and that the relevant term was thus indefinite. *Id*. at 697-98.

The same result follows here: the '952 Patent has a term which could be ascertained by different measures, those measures could yield different results, and neither intrinsic nor extrinsic evidence indicates which to use. The term is thus indefinite.

The cases that Ingenus relies on do not compel a different outcome. In *Cadence*, the district court used an older and more "exacting" test for indefiniteness that

required a determination that a claim term is "insolubly ambiguous . . . such that it is incapable of construction." *Cadence Pharms., Inc. v. Paddock Lab'ys Inc.*, 886 F. Supp. 2d 445, 452 (D. Del. 2012), *aff'd sub nom. Cadence Pharms. Inc. v. Exela PharmSci Inc.*, 780 F.3d 1364 (Fed. Cir. 2015). Notwithstanding that *Cadence* applied a test no longer in effect, the court found the term "stable" to be definite in part because the methods that the patent identified to assess stability would not lead to varying results. *Id.* at 452-53. In *Medimmune*, a defendant challenged the definiteness of the term "thermally-stable" at claim construction. *Medimmune Oncology, Inc. v. Sun Pharm. Indus., Ltd., No. CIV.A.* MJG-04-2612, 2007 WL 6137013, at *5 (D. Md. Oct. 29, 2007). There, the district court explicitly declined to address definiteness. *Id.* Rather, the court construed the term stable based on the single refrigerated conditions test present in the patent's specification. *Id.* at *5 - *7. In *Senju*, a district court found the term "stable" to be definite, but the court explained that it did so "[p]articularly with the benefit of Experimental Examples that illustrate the exact testing conditions and results at which the solution would be acceptable . . .". *Senju Pharm. Co. v. Lupin Ltd.*, 162 F. Supp. 3d 405, 417 (D.N.J. 2015). Such "exact testing conditions and results" are missing from the '952 Patent. The remaining cases cited by Ingenus similarly either rely on an outdated and more exacting legal test or, like *Senju*, serve to highlight the deficiencies in the '952 Patent.

Ingenus separately argues that because Nexus appeared to understand and apply a rigorous definition of the word "stable" in its own ANDA, the word cannot be indefinite. But whether Nexus was able to put forth a definitive meaning of the word

"stable" is irrelevant to whether "stable," as used in the '952 Patent, is indefinite to a POSA. To be clear, the Court does not hold here that the word stable can *never* be definite as applied to formulations of cyclophosphamide or any other pharmaceutical. Rather, the term *as used in the '952 Patent* is too indefinite to provide a POSA notice of what is claimed.

Ingenus also argues in its opposition brief that "stable" can be readily construed to mean "having sufficient resistance to degradation so as to be useful for parenteral administration over its shelf life." This construction raises more questions than it answers. It does not explain how "sufficient resistance" should be measured (e.g., whether through the weight of impurities A, B, D, or any of the other impurities measured in Table 1, or any of the other numerous aspects of stability that Ingenus and its experts have put forth). Further, and unlike other cases that have construed a similar definition of "stable," the patent does not identify the "shelf life" of the pharmaceutical or explain how to evaluate whether the formulation is useful its shelf life. *See Senju*, 162 F. Supp. 3d at 417 (adopting a similar definition but only "with the benefit of . . . the exact testing conditions and results at which the solution would be acceptable."). The focus on "shelf life" also appears misplaced, because the only stability testing data in the patent measures stability after just one week. Finally, such a definition would be contrary to Dr. Rabinow's stated position that the patent claims stability under both the Accelerated Conditions Test and Refrigerated Conditions.

For these reasons, Nexus's motion for summary judgment [132] is granted.

II. Infringement

The Court turns next to Ingenus's motion for summary judgment on its infringement claim. The parties dispute whether a party can succeed on a patent infringement claim if a term in the patent has not yet been construed, and they further dispute the effect of a finding that a claim term is indefinite. Ingenus argues that infringement and invalidity are entirely separate questions and that the Court could find Nexus has infringed on the '952 Patent without regard to its validity. In support, Ingenus relies primarily on the Supreme Court's decision in *Commil* and the Federal Circuit's decision in *Pandrol*. In *Commil*, the Supreme Court stated that "[w]hen infringement is the issue, the validity of the patent is not the question to be confronted." *Commil USA, LLC v. Cisco Sys., Inc.,* 575 U.S. 632, 643 (2015). In *Pandrol*, the Federal Circuit similarly stated that "patent infringement and patent validity are treated as separate issues." *Pandrol USA, LP v. Airboss Ry. Prods., Inc.*, 320 F.3d 1354, 1365 (Fed. Cir. 2003).

At least some district courts have accepted Ingenus's reading of these cases and held that a patentee can succeed in their infringement claim even when their patent is invalid. *See, e.g., Robertson Transformer Co. v. GE*, 191 F. Supp. 3d 826, 841-42 (N.D. Ill. 2015) (granting plaintiff's motion for summary judgment on patent infringement after finding that the patent-in-suit is invalid). Respectfully, the Court does not believe that *Commil*, *Pandrol*, or any other precedential decision goes that far. In *Commil*, which the *Robertson* court relied on, the Supreme Court considered the narrow question of whether a defendant's belief regarding the validity of a patent

was a defense to a claim of induced infringement. 575 U.S. at 642. Despite acknowledging that validity and infringement are different questions, the Court explained that "noninfringement ***and invalidity*** [are] 'alternative grounds' for dismissing" an infringement suit. *Id*. (citing *Cardinal Chemical Co. v. Morton Int'l, Inc.*, 508 U.S. 83 (1993) (emphasis added)). *Commil* also approvingly cited the Supreme Court's earlier decision in *Deposit Guaranty Nat. Bank v. Roper*, where the Court held that an accused infringer "may prevail either ***by successfully attacking the validity of the patent*** or by successfully defending the charge of infringement." 445 U.S. 326, 334 (1980) (emphasis added).

And in *Pandrol*, the Federal Circuit addressed the narrow question of whether an alleged infringer waived its ability to raise invalidity as a defense by failing to raise it in response to the patentee's motion for summary judgment for infringement. 320 F.3d at 1364. Despite acknowledging that infringement and validity are separate questions, *Pandrol* did not suggest that the validity of a patent has no bearing on its alleged infringement, as Ingenus suggests. Rather, the court held only that because invalidity is a separate issue from infringement, failure to raise invalidity did not constitute a waiver. *Id*. at 1365. *Pandrol* itself cited the Federal Circuit's earlier decision in *Medtronic*. There, while reviewing a district court's determination that a patent was invalid and that the claims in suit were thus necessarily not infringed, the Federal Circuit noted in dicta that it would have been the "better practice" to decide both issues separately. *Medtronic, Inc. v. Cardiac Pacemakers, Inc.*, 721 F.2d 1563, 1583 (Fed. Cir. 1983). *Medtronic* explained that the Federal Circuit preferred

that invalidity and infringement be separately decided to avoid the need to remand the decision back to the district court if the Federal Circuit reversed the lower court's invalidity finding. *See id.*[5] It did *not* hold that an infringement claim can succeed when the underlying patent is invalid.

Several other cases make clear that a patent cannot be infringed unless its terms are defined. *See, e.g.*, *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 374 (1996) ("Victory in an infringement suit requires a finding that the patent claim covers the alleged infringer's product or process, which in turn necessitates a determination of what the words in the claim mean.") (internal quotations removed); *Intellectual Sci. & Tech., Inc. v. Sony Elec., Inc.*, 589 F.3d 1179, 1183 (Fed. Cir. 2009) ("Literal infringement first requires the trial court to interpret the claims to determine their scope and meaning."). This approach is also reflected in the plain text of the Patent Act, which lists "[i]nvalidity of the patent or any claim in suit" as a "defense[] in any action involving the validity or infringement of a patent." 35 U.S.C. § 282(b).

In short, because an "invalid claim can not be infringed," *Viskase Corp. v. Am. Nat. Can Co.*, 261 F.3d 1316, 1323 (Fed. Cir. 2001), and because all the claims in the '952 Patent either implicitly or explicitly contain the indefinite term "stable," Ingenus's motion for summary judgment [130] is denied.

CONCLUSION

[5] To the extent that *Medtronic* suggests that the Court should assess whether Ingenus would succeed on its infringement claim if the term "stable" were not indefinite, the Court declines to do so.

For the stated reasons, Nexus's motion for summary judgment based on invalidity [132] is granted, and Plaintiffs' motion for summary judgment for infringement [130] is denied. The Clerk is directed to enter judgment in Nexus's favor and against Plaintiffs and terminate the case.

E N T E R:

Dated: May 9, 2025

MARY M. ROWLAND
United States District Judge